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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,066	10/18/2001	Frederick M. Ausubel	00786/387003	3890

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EXAMINER
PARAS JR, PETER

ART UNIT	PAPER NUMBER
1632	6

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,066	AUSUBEL ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) *12-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-86 are pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-11, in Paper No. 5 is acknowledged.

Claims 12-86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. The reference to prior applications in the instant application is not in the first sentence of the specification.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Drawings

New corrected drawings are required in this application because the drawings as filed appear to be photocopies and have a background high level that reduces the clarity of the drawings. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 12 of the specification as it contains an embedded hyperlink.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are directed to methods of identifying a nematode having enhanced susceptibility to a pathogen comprising exposing a mutagenized nematode to a pathogen and determining the survival of said mutagenized nematode, wherein the mutagenized nematode has a mutation in a component of a MAPK signal transduction pathway.

The claimed invention is directed to a method of identifying nematodes, particularly *C. elegans*, having an enhanced susceptibility to a pathogen. In particular, the specification suggests that nematodes having an enhanced susceptibility to a pathogen comprise mutations in a component of a MAPK signal transduction pathway. The specification has asserted the disclosed utilities for a nematode identified by the claimed methods include identification of other members of the MAPK signaling cascade or screening to identify therapeutic compounds, which can be used to promoter or enhance the ability of a host to combat pathogen infection or block pathogen virulence. See pages 5-6. The specification further asserted an identified "therapeutic" compound provides an effective therapeutic agent in a mammal. See page19.

However, the specification fails to provide a specific and substantial utility for the claimed methods or the nematodes identified therefrom. Neither the specification nor any art of record teaches establishes a relationship of a susceptible nematode to any specific mammalian disease or establishes any involvement of any component of the nematode, particularly *C. elegans*, MAPK pathway in the etiology of any specific disease affecting mammals. Although the specification has contemplated that the claimed methods can identify nematodes, susceptible to pathogen infection that are useful for identifying compounds that may potentially treat mammalian diseases related to infection by a pathogen, no evidence has been presented that relates nematode and mammalian disease states caused by pathogen infections such that any agent identified in the nematode system of the invention would be understood as therapeutic with respect to a correlative mammalian disease. No evidence has been presented that correlates nematode pathogens with mammalian pathogens such that it is understood that nematodes and mammals are susceptible to the same pathogens.

A substantial utility is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities under §101. Applicant's specification fails to provide a "real world" use of the claimed methods such that the any nematode identified by such methods additionally has no "real world" use. Neither the specification as filed, nor any art of record disclose or suggest any correlation between an identified susceptible nematode and a mammalian disease such that any utility would be well established for the nematode. The asserted utilities for any identified nematodes such

as identification of other members of the MAPK signaling cascade or screening to identify therapeutic compounds, which can be used to promoter or enhance the ability of a host to combat pathogen infection or block pathogen virulence are merely "potential" uses that apply to any nematode. Therefore the asserted utilities are not considered "specific" utilities, i.e. they are not specific to the claimed invention.

The asserted utility of SEQ ID NO:2 is based on the assertion that susceptibility of a nematode, comprising a mutation in a component in a MAPK pathway, to a pathogen is correlative to a mammalian disease state. The specification has not provided any evidence that such a correlation exists that would allow identification of "therapeutic" agents for mammalian diseases by way of the susceptible nematodes. Moreover, the specification has failed to provide evidence of correlations between nematode and mammalian diseases or pathogens, particularly as they relate to the MAPK signal transduction pathway, to support such assertions. In any event, assuming the assertions of the instant specification are correct and that a mutation in a component of a *C. elegans* MAPK pathway correlates to a mammalian disease state, it is unclear exactly which disease state correlates to which mutated MAPK pathway component. The MAPK pathway is comprised of many members, which have different chemical structures, different specificities, different activators and inhibitors, and more importantly different substrates. See Garrington et al (Current Opinion in Cell Biology, 1999, 11: 211-218) which further reports that MAPKs contribute to complex regulatory events including mitogenesis, differentiation, survival, and migration. See page 211.

Garrington et al demonstrates the biochemical diversity MAPK pathway members. However, neither the specification nor any art of record has taught what component of the MAPK pathway when mutated in a nematode correlates to a mammalian disease state leaving the skilled artisan to speculate and investigate the uses of the claimed methods and nematodes identified therefrom. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the claimed methods and nematodes identified therefrom. In view of the lack of guidance with respect to the diseases the claimed invention encompasses, the skilled artisan would not know how to use the claimed methods or nematode identified therefrom. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to methods of identifying a nematode having enhanced susceptibility to a pathogen comprising exposing a mutagenized nematode to a pathogen and determining the survival of said mutagenized nematode, wherein the mutagenized nematode has a mutation in a component of a MAPK signal transduction pathway.

The components of the MAPK signal transduction pathway which when mutated result in a nematode having susceptibility to a pathogen, other than esp-8 and pmk-1, encompassed within the genus have not been disclosed. Based upon the prior art there is expected to be variation among the species of components of the MAPK pathway, because of the diversity of the components of the MAPK pathway. The specification discloses that mutations in esp-8 and pmk-1 result in susceptibility of a nematode to a pathogen but does not disclose other components of the MAPK pathway that correlate to susceptibility to a pathogen. There is no evidence on the record of a relationship between the structure of any MAPK component and esp-8 or pmk-1 that would provide any reliable information about the structure of other MAPK components within the genus. There is no evidence on the record that the disclosed MAPK components had known structural relationships to any other MAPK components; the art indicated that

there is much diversity among MAPK components. There is no evidence that mutating any of the other MAPK components would result in susceptibility of a nematode to a pathogen. In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus, because esp-8 and pmk-1 are not representative of the claimed genus. Consequently, since Applicant was in possession of only nematodes comprising mutations in esp-8 and pmk-1 and since the art recognized variation among the species of the genus of MAPK components, the disclosed nematodes and MAPK components were not representative of the claimed genus. Therefore, Applicant was not in possession of the genus nematodes comprising mutated MAPK components as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.
Art Unit 1632

PETER PARAS
PATENT EXAMINER